K063511

FEB - 2 2007

EXHIBIT 2

510(k) SUMMARY: Amann Girrbach America, Inc. Ceramill Zi Blanks

This 510(k) summary of safety and effectiveness for Amann Girrbach America, Inc. Ceramill Zi Blank material is submitted in accordance with the requirements of SMDA 1990 and follows Office of Device Evaluation guidance concerning the organization and content of a 510(k) summary.

Applicant: Amann Girrbach America, Inc

Address: 12169 Villa Road
Spring Hill, FL 34609
Tel 800 851-3719
Fax 352-398-1409
Contact Person: Ms. Amanda Clark

Manufacturer: Amann Girrbach GmbH
Herschaftsweisen 1
Koblach 6842-A Austria

Preparation Date: November 16, 2006

Device Name: Ceramill Zi Blank
Common Name: Dental Frame Material for Dental Prosthesis
Classification: Porcelain, powder for clinical use
21 CFR 872.6660
Class II medical device
Product Code: EIH
Panel: 76

Predicate devices: KaVo Everest ZS-Blank K03281 and 3M "Lava" K053438 and Vident VITA IN-CERAM 2000 AL CUBES FOR INLAB, MODELS AL2 K052130 and ZIRKONZAHN GMBHZIRKONZAHN ICE K061851, among others.

Device description: The Ceramill Zi Blank is a pre-formed material for use by dental laboratories in filling orders/prescriptions for dental prosthetics

Indications: The Ceramill Zi Blank is used in the manufacture of dental prosthetics.

Performance Data: None required. The claim of substantial equivalence is based on comparisons of formulations, mechanical characteristics, and intended uses of the devices to legally marketed predicates and to the IDENTIFICATION of porcelain powders in 21 CFR 872.6660.

CONCLUSION: Based on the information in the notification Amann Girrbach America, Inc believes that Ceramill Zi Blank is substantially equivalent to cited legally marketed predicates and to the IDENTIFICATION in the classifying regulation (21 CFR 872.6660).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Amann Girrbach America, Incorporated
C/O Mr. Daniel Kamm
Principal Consultant
Kamm & Associates
P.O. Box 7007
Deerfield Illinois 60015

FEB - 2 2007

Re: K063511
Trade/Device Name: Ceramill Zi Blanks
Regulation Number: 872.6660
Regulation Name: Porcelain Powder for Clinical Use
Regulatory Class: II
Product Code: EIH
Dated: November 16, 2006
Received: November 21, 2006

Dear Mr. Kamm:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

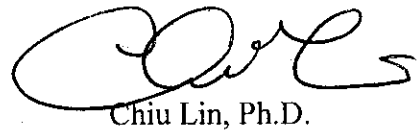
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K063511

Indications for Use

510(k) Number (if known): K063511

Device Name: Ceramill Zi blanks .

Indications for Use:
Amann Girrbach America, Inc. Ceramill Zi blanks are used in the manufacture of dental prosthetics.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

(Division Sign-Off)
(Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices
510(k) Number K063511